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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|-------------------------|------------------|
| 09/776,935 | 12/22/1998 | JACQUES DUMAS | BAYER 12P1 | 7400 |
| 7: | 590 06/15/2005 | EXAM | EXAMINER | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. ARLINGTON COURTHOUSE PLAZA I 2200 CLARENDON BOULEVARD SUITE 1400 | | | MITCHELL, GREGORY W | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| ARLINGTON, | VA 22201 | | DATE MAILED: 06/15/2005 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|--|--|---|--|--|--|
| | 09/776,935 | DUMAS, JACQUES | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Gregory W. Mitchell | 1617 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 16(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONED | ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on <u>17 March 2005</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☐ This | action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) ⊠ Claim(s) 1-30 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-30 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examine | r. | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | | atent Application (PTO-152) | | | |

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DETAILED ACTION

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This Office Action is in response to the Remarks and Amendments filed March 17, 2005. Claim 1 has been amended. Claims 1-30 are pending and are examined herein.

The IDS submitted March 17, 2005 is a duplicate of the IDS submitted December 20, 2002. Office records indicate that a signed copy of the 1449 was mailed November 18, 2003. Examiner faxed a copy of the signed 1449 to Applicant on June 01, 2005.

It is noted that the current claims are subject to a species requirement, set forth in the Office Action mailed August 01, 2001, for both a single disease and a single compound. Applicant has elected rheumatoid arthritis as the single disease and in the Office Action dated January 11, 2005, Examiner expanded Applicant's elected compound to encompass the genus of compounds encompassed by the formula:

It is further noted that Applicant's amendment to claim 1 is sufficient to overcome Examiner's objection thereto. Art Unit: 1617

35 USC § 103 Rejection Maintained

Claims 1-30 stand rejected under 35 USC 103 for the reasons set forth in the Office Action dated January 11, 2005 as being obvious over Creswell et al. (USPN 5162360) in view of Adams et al. (USPN 5658903).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that because the diazoles of Adams et al. are not sufficiently similar to the instantly claimed that the claims are not obvious. This argument is not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is noted that Examiner does not rely on Adams alone in the 35 USC 103 rejection over the instant claims. Examiner relies on Creswell et al. to teach that the claimed compounds are known for the treatment of atherosclerosis (a disease known to be mediated by p38). Examiner relies on Adams et al. to show that both atherosclerosis and rheumatoid arthritis are known to be similarly treatable and are both known to be mediated by p38.

Applicant's argument that Adams et al. "does not teach that atherosclerosis is a p38 mediated disease" is not persuasive. Applicant's attention is drawn, specifically, to col. 65, lines 29-31.

Applicant argues, "Whether Adams teaches that atherosclerosis is a p38 mediated disease or whether it was otherwise known in the art to be a p38 mediated

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disease is not relevant to the issue of obviousness. Such information, does not teach or suggest that the compounds of Creswell are effective in inhibiting p38 and in treating p38 mediated diseases, since such information does not exclude the possibility that other pathways may mediate atherosclerosis." This argument is not persuasive. First of all, it is noted that Applicant is arguing limitations that are not in the claims. The claims are directed to treating a disease mediated by p38, which both atherosclerosis and rheumatoid arthritis are known to be, not that the disease must be one that may not also be mediated by other pathways. Furthermore, it is respectfully pointed out that the fact that the treatment of rheumatoid arthritis with the claimed compounds is rendered obvious by the prior art would be sufficient to meet the claims even without a teaching that atherosclerosis and/or rheumatoid arthritis are p38 mediated diseases because the discovery of a new pathway for the treatment of the same disease with the same compounds does not render the same treatment patentable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER